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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/854,435	05/11/2001	Steven Y. Ng	10008-1191	7251

25213 7590 09/27/2002

HELLER EHRMAN WHITE & MCAULIFFE LLP  
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MENLO PARK, CA 94025-3506

EXAMINER

ACQUAH, SAMUEL A

ART UNIT	PAPER NUMBER
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1711

DATE MAILED: 09/27/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/854,435

Applicant(s)

NG ET AL.

Examiner

SAMUEL A. ACQUAH

Art Unit

1711

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on 13 August 2001 and 25 September 2002.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-35 is/are pending in the application.
- 4a) Of the above claim(s) 20-35 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-19 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

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## DETAILED ACTION

### *Election/Restrictions*

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-19, drawn to a polyorthoester and method of making, classified in class 528, subclass 220.
- II. Claims 20-35, drawn to a device for orthopedic restoration and bioerodible implants, classified in class 424, subclass 422.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product can be used to make thermoplastic elastomers or the process can be practiced with polyorthoesters not containing nitrogen bonds.

3. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

4. During a telephone conversation with Derek P. Freyberg on 09/25/02 a provisional election was made with traverse to prosecute the invention of a polyorthoester and method of making, claims 1-19. Affirmation of this election

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must be made by applicant in replying to this Office action. Claims 20-35 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 1-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Heller et al '543 combined with Sparer et al '010.

The primary reference, common-inventor patent to Heller et al disclose polymers with controlled physical state and bioerodibility. The polymer is made from a diketene acetal, and the polymer chain incorporates esters of alpha-hydroxy acid and diols as claimed. There is no disclosure of the use of diols containing functional groups selected from amide, imide, etc. as claimed. It is the Examiner's position that the use of as indicated would have been obvious in view of the secondary reference to Sparer et al which discloses bioerodible poly(ortho ester) thermoplastic elastomer from diketene diacetal and mixture of diols which

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may contain functionalities capable of engaging in hydrogen bonding, such as amides, urethanes, urea, and imides. Thus, the preparation of polyorthoesters incorporating structural units as claimed would have been prima facie obvious based on a combination of the references as explained supra.

8. Claims 1, 17, and 18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are drawn to an improper Markush practice by the recitation of "selected from...".

9. Other references listed on PTO-1449 have been made part of the record.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to SAMUEL A. ACQUAH whose telephone number is 703-308-2436. The examiner can normally be reached on M-TH, FRIDAYS OFF.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, JAMES SEIDLECK can be reached on 703-308-2462. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-7718 for regular communications and 703-872-9311 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-305-0661.

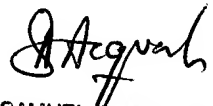
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S.A.A.

September 25, 2002

  
SAMUEL A. ACQUAH  
PRIMARY EXAMINER  
GROUP ~~1200~~ / 700

COPY

<b>INFORMATION DISCLOSURE STATEMENT</b> (37 CFR 1.56, 1.97, and 1.98)  SHEET 1 OF 1				ATTORNEY DOCKET 10008-1191		APPLICATION NO. 09/854,435	
				APPLICANT(S) Steven Y. Ng et al.			
				FILING DATE May 11, 2001		GROUP 1614	
<b>U.S. PATENT DOCUMENTS</b>							
† EX'R INITIAL	* REF. #	PATENT NUMBER	DATE (MO/YR)	NAME	CLASS/ SUBCLASS	FILING DATE (If appropriate)	
	1	4,079,038	03/1978	Choi et al.	260/47XA		
	2	4,093,709	06/1978	Choi et al.	424/19		
	3	4,131,648	12/1978	Choi et al.	424/22		
	4	4,138,344	02/1979	Choi et al.	252/1		
	5	4,180,646	12/1979	Choi et al.	528/153		
	6	4,304,767	12/1981	Heller et al.	424/78		
	7	4,532,335	07/1985	Helwing	549/335		
	8	4,549,010	10/1985	Sparer et al.	528/361		
	9	4,946,931	08/1990	Heller et al.	528/230		
	10	4,957,998	09/1990	Heller et al.	528/220		
	11	5,518,730	05/1996	Fuisz	424/426		
	12	5,620,697	04/1997	Törmälä et al.	424/426		
	13	5,968,543	10/1999	Heller et al.	424,425		
	14	6,046,187	04/2000	Berde et al.	514/180		
<b>FOREIGN PATENT DOCUMENTS</b>							
† EX'R INITIAL	* REF. #	PATENT NUMBER	DATE (MO/YR)	COUNTRY	TRANSLATION (YES/NO)		
<b>OTHER DOCUMENTS</b>							
† EX'R INITIAL	* REF. #	Citations(Author Title, Journal/Book Title, Date, Pertinent Pages, etc.)					
	15	"Semi-solid delivery vehicle and pharmaceutical compositions", US Patent Application No. 09/854,180, filed May 11, 2001					
EXAMINER'S SIGNATURE 				DATE CONSIDERED 9/25/02			
† EXAMINER: Initial if reference is considered, whether or not citation is in conformance with MPEP 609. Line through citation if not in conformance and not considered. Include copy of this form in next communication to applicant. * If an asterisk is placed beside the reference number, a copy is not provided because the reference was previously cited by or submitted to the PTO in a prior application that is identified in the statement and relied upon for an earlier filing date under 35 U.S.C. 120. 37 C.F.R. 1.98(d).							

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**INFORMATION DISCLOSURE STATEMENT**

(37 CFR 1.56, 1.97, and 1.98).

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Attorney Docket 10008-1191	Application No. 09/854,435
Applicant(s) Steven Y. Ng et al.	
Filing date May 11, 2001	Art Unit 1614

**U.S. PATENT DOCUMENTS**

† Ex'r initial	* Doc. #	Patent No.	Date (month/year)	Name	Class/Subclass	Filing date (if appropriate)
<i>SH</i>	1	4,549,010	10/1985	Sparer et al.	528/361	
<i>SH</i>	2	5,968,543	10/1999	Heller et al.	424/425	

**FOREIGN PATENT DOCUMENTS**

† Ex'r initial	* Doc. #	Country	Patent No.	Date (month/year)	Applicant	Translation
<i>SH</i>	3	WO	01/85139 A2	11/2001	Advanced Polymer Systems, Inc.	

**OTHER DOCUMENTS**

† Ex'r initial	* Doc. #	Citation (Author, Article Title, Journal/Book Title, Date, Pertinent Pages, etc.)
<i>SH</i>	4	J. Heller et al., "Poly(ortho esters) - their development and some recent applications", <i>Eur. J. Pharmaceutics Biopharmaceutics</i> , 50(1), 121-138 (2000)
<i>SH</i>	5	S.Y. Ng et al., "Development of a poly(ortho ester) prototype with a latent acid in the polymer backbone for 5-fluorouracil delivery", <i>J. Controlled Release</i> , 65(3), 367-374 (2000)
<i>SH</i>	6	M.B. Sintzel et al., "Synthesis and characterization of self-catalyzed poly(ortho ester)", <i>Biomaterials</i> , 19(7-9), 791-800 (1998)

Examiner's signature <i>Sam A. Stewart</i>	Date considered 9/25/02
† EXAMINER: Initial if reference is considered, whether or not citation is in conformance with MPEP 609. Line through citation if not in conformance and not considered. <i>Include copy of this form in next communication to applicant.</i> * If an asterisk is placed beside the reference number, a copy is not provided because the reference was previously cited by or submitted to the PTO in a prior application that is identified in the statement and relied upon for an earlier filing date under 35 U.S.C. 120. 37 C.F.R. 1.98(d).	